APR 2 1 2013

Exhibit #4 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K123483

1. Date of Submission: Nov 10, 2012

2. Sponsor

Beijing Syntech Laser Co., Ltd
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3. Submission Correspondent

Ms. Diana Hong & Mr. Tarzan Wang
Mid-Link Consulting Co., Ltd
P.O. Box 237-023, Shanghai, 200237, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Trade Name: Diode Laser
Proposed Device Model: DLH-06
Proposed Device Common Name: Laser System
Proposed Device Classification name: Powered Laser Surgical Instrument
Classification: II

Product Code: GEX
Regulation Number: 21 CFR 878.4810
Review Panel: General& Plastic Surgery
Intended Use Statement:
The Diode Laser is intended for use in dermatologic and general surgical procedures.
The Standard Mode is intended for hair removal, permanent hair reduction.
The FHR Mode is intended for hair removal, permanent hair reduction.
The diode laser system is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

5. Predicate Device Identification

510(k) Number: K112031
Product Name: Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platforms.
Manufacturer: Alma Lasers, Inc.

6. Device Description

The diode laser is a surgical device intended for use in dermatologic and general surgical procedure. It utilizes a semiconductor diode with invisible infrared radiation as a laser source (808 nm). The laser power is delivered to the treatment area via a laser handpiece. The emission laser is activated by a footswitch.

The diode laser emits 808nm wavelength laser which is absorbed by melanin and at the same time greatly reduce the absorption by water and haematoglobin. The laser beam penetrates through epidermis into dermis and absorbed by melanin in hair and hair follicle, producing laser photothermal effect, conducting the energy from hair section to hair toot, rising temperature of melanin and decomposing it, thus reaching effect of hair removal.

During treatment, the Sapphire in handpiece assures reliable and constant cooling result for skin surface with the maximum comfort and safety. When the laser system starts to release energy, skin cooling system works automatically. The cooling system reduces the temperature of treatment area and increase treatment comfort.

The proposed device includes power supply system, central control system, cooling system, laser deliver system and safety feature.

The cover material of the proposed device is ABS (Acrylonitrile Butadiene Styrene) plastic. The patient contact components in laser handpiece include supporting plate which is made of stainless steel and

crystal which is made of sapphire.

Tab. III-1 device specification

Item	Specification
Light type	Diode laser
Wavelength (nm)	808
Fluence (J/cm^2) max	≤10 (FHR)
	≤120 (Standard)
Beam divergence (mard)	10 (short side),40 (long side)
Spot Size (mm)	12 X 10
Pulse width (ms)	≤20 ms(FHR)
	5-200 ms (Standard)
Repetition rate (Hz)	≤10 Hz(FHR)
	≤3 Hz(Standard)
Skin cooling	Contact cooling
Dimensions (D X W X H,mm)	460X 365 X350
Weight (kg)	26 kg
The energy measurement comparison between plan to use and leave the factory	-0.03% per working time
Cumulative measurement uncertainty	U=2%(k=2)

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1-1:1988+A1:1991+A2:1995, Medical Electrical Equipment- Part 1: General requirements for safety.

IEC 60601-2-22: 1995, Medical Electrical Equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.

IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements.

IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.

ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity

ISO 10993-10:2002/Amd. 1: 2006, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1

8. Technological Characteristics Comparison

Tab. III-2 Technology Characteristics Comparison

ITEM	Proposed Device		Predicate Device K112031	
Light type	Diode laser		Diode laser	
Wavelength (nm)	808 nm		810 nm	
Spot size	1.2 cm^2		same	
Diode Module Mode	FHR Mode	Standard Mode	SHR Mode (Super Hair Removal)	HR Mode
Indications for Use	Intended for hair removal, permanent hair reduction	Intended for hair removal, permanent hair reduction	Intended for hair removal, permanent hair reduction	Intended for hair removal, permanent hair reduction
Fluency (energy density)	≤ 10 J/cm^2	≤ 120 J/cm^2	same	same
Repetition Rate	≤10 Hz	≤3 Hz	same	same
Pulse Duration	≤ 20 ms	5-200 ms	same	Same
Dimension	460 mmx365 mmx350mm (D x W x H)		20" x22.4"x47" (494mm x569mm x 120mm)	
Weight	26 kg		110 lbs.(49 kg)	

9. Substantially Equivalent Conclusion

The wavelength of proposed device is similar as that of the predicate; the slight difference of 2 nm will not raise new problems in safety and Effectiveness; The treatment modes and their corresponding IFU of the proposed device are covered by those of predicate device; therefore this item is considered to be substantially equivalency; there is difference on the dimension and weight between proposed device and predicate device, the physical specification will not raise new problem in safety and effectiveness

The proposed device, Diode Laser, is determined to be Substantially Equivalent (SE) to the predicate device, Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platform (K112031) in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 21, 2013

Beijng Syntech Laser Co., Ltd.
% Mid-Link Consulting Co., Ltd.
Ms. Diana Hong, General Manager
P.O. Box 237-023
Shanghai, 200237, China

Re: K123483
Trade/Device Name: Diode Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 21, 2013
Received: April 01, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #5 Indications for Use

510(k) Number:
Device Name:

Indications for Use:

The Diode Laser is intended for use in dermatologic and general surgical procedures.
The Standard Mode is intended for hair removal, permanent hair reduction.
The FHR Mode is intended for hair removal, permanent hair reduction.
The diode laser system is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.04.19 16:22:03 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K123483